Continuous low-dose aspirin therapy in robotic-assisted laparoscopic radical prostatectomy does not increase risk of surgical hemorrhage

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Abstract: Abstract Background: Withdrawal of oral antiplatelet therapy (OAT) is a major risk factor for stent thrombosis, myocardial infarction, and cerebral strokes. In order to minimize the risk for thrombotic complications, since 2007 robotic-assisted laparoscopic radical prostatectomy (RARP) has taken place under continuous OAT with aspirin at our institution. In this retrospective study we analyzed the risk for perioperative bleeding and surgical outcome after RARP with OAT. Patients and Methods: All patients who underwent RARP with aspirin OAT at our institution since 2007 were included in this analysis. The OAT group was compared with a group that underwent RARP without OAT, which contained twice the number of patients. Matching of the two groups was performed with regard to the tumor stage and whether a lymph node dissection or nerve-sparing was performed. Results: Thirty-eight patients were assigned to the OAT group and 76 to the control group. A difference in the decrease of postoperative hemoglobin concentration was not detectable between the two groups (mean drop of 2.9±1.4 g/dL and 2.9±1.1 g/dL, respectively; P=.93). RARP was completed in all OAT patients without conversion to open surgery. Two of the 38 patients (5.3%) in the OAT group and none in the control group required blood transfusions (P=.11). Equivalent rates of positive surgical margins for pT2 tumors were detected (16% OAT versus 14% control group; P=1.0). No adverse cardiovascular events occurred in either group during the hospitalization. Conclusions: Continued perioperative OAT with aspirin in RARP is safe, feasible, and not associated with increased blood loss.

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Full Report

Continuous Low-Dose Aspirin Therapy in Robotic-Assisted Laparoscopic Radical Prostatectomy Does Not Increase Risk of Surgical Hemorrhage

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Abstract

Background: Withdrawal of oral antiplatelet therapy (OAT) is a major risk factor for stent thrombosis, myocardial infarction, and cerebral strokes. In order to minimize the risk for thrombotic complications, since 2007 robotic-assisted laparoscopic radical prostatectomy (RARP) has taken place under continuous OAT with aspirin at our institution. In this retrospective study we analyzed the risk for perioperative bleeding and surgical outcome after RARP with OAT.

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Conclusions: Continued perioperative OAT with aspirin in RARP is safe, feasible, and not associated with increased blood loss.

Introduction

The number of patients with cerebrovascular or coronary heart disease is growing, and the use of coronary stents and antiplatelet drugs is increasing.[1] Accordingly, increasing numbers of patients presenting for surgery are treated with antiplatelet medication. Five percent of patients receiving an intracoronary stent will undergo noncardiac surgery within the first year after intervention.[2] Depending on the type of stent, patients may require single or dual oral antiplatelet therapy (OAT) for a certain time period, either with aspirin (acetylsalicylic acid) alone (montherapy) or in combination with a second antiplatelet agent, most commonly an ADP receptor antagonist such as clopidogrel (dual therapy). The current guidelines recommend 1 month of dual antiplatelet therapy after a bare-metal coronary stent and 1 year of dual antiplatelet therapy after a drug-eluting coronary stent.[3] Lifelong continuation of aspirin after this time period is highly recommended.[4] Other indications for a lifelong secondary prophylaxis (preventing the recurrence of the disease) with aspirin are stroke, angina pectoris, myocardial infarction, or endovascular/open revascularization.[4]

The interruption of OAT during invasive, noncardiac procedures in patients with coronary stents is associated with a

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high risk of cardiovascular complications.[5–7] Despite this, perioperative withdrawal of antiplatelet therapy is still widely practiced. Urologists often tend to discontinue the antiplatelet therapy because of concerns of increased intraoperative or postoperative bleeding complications.[8] Nevertheless, thromboembolic complications such as myocardial infarction and cerebral strokes are often irreversible and have a significant morbidity and mortality.[5]

Radical prostatectomy is an elective surgical procedure with the potential for significant blood loss.[9] Therefore, current recommendations suggest postponing radical prostatectomy whenever possible and performing it later without any type of OAT or choosing a noninvasive therapy.[10] However, the increased blood loss due to OAT with aspirin may be minimized by using a minimally invasive (laparoscopic), meticulous surgical technique and may be compensated for by intense postoperative monitoring and transfusions if necessary. Robotic-assisted laparoscopic radical prostatectomy (RARP) has been performed under continuous OAT with low-dose aspirin for secondary prevention at our institution since 2007 to minimize the risk of fatal thromboembolic complications. In this retrospective investigation, we analyzed the risk for perioperative bleeding and assessed the surgical outcome after RARP performed with continued OAT.

Patients and Methods

Patient selection and matching

A retrospective electronic chart review of patients at our institution from March 2007 to October 2012 identified all patients who underwent RARP under continuous OAT with low-dose aspirin (100 mg/day) (OAT group). Documentation of continued OAT before admission and intake of aspirin on the day of surgery were required criteria for inclusion in the OAT group. Patients taking other antiplatelet agents were excluded. This group was compared with a double-sized, randomly matched sample of RARP patients without OAT (the control group). Matching of the two groups was performed with regards to tumor stage (pT) and whether a lymph node dissection or nerve-sparing was performed. Approval for this retrospective study was given by the Internal Review Board (protocol number USZ-917).

Surgical technique

RARPs were performed using the four-arm daVinci® Surgical System (Intuitive Surgical Inc., Sunnyvale, CA) by a transperitoneal approach. Indications for the bilateral extended pelvic lymph node dissection (EPLND) were either a prostate-specific antigen level of $\geq$10 ng/mL or a preoperative Gleason score of $\geq$7. Boundaries of the EPLND have been described previously.[11] After identification of important landmarks, the lymphatics covering the external iliac vein, the obturator lymphatic packet, and the lymphatics overlying the internal iliac artery were removed on both sides.

Once the EPLND was completed, the extraperitoneal space was entered through lateral mobilization of the bladder, and an incision of the endopelvic fascia was made to gain access to the lateral surface of the prostate. After preparation of the ventral part of the prostate, ligation of the Santorini plexus was performed. Following dissection of the bladder neck in a straight line down to the pillars (antegrade approach), the seminal vesicles were removed completely, and the dorsal surface of the prostate was released. In the case of a nerve-sparing approach, the preparation of the neurovascular bundle was performed with clips and without coagulation to avoid thermal damage to the nerve fibers. After careful preparation of the apex, the prostate was removed. A posterior musculofascial plate reconstruction according to Rocco et al.[12] was completed, and finally the vesicourethral anastomosis was performed with running or interrupted sutures. On postoperative Day 5, cystography was performed, and the urinary catheter was removed if no vesicourethral leak was detected.

Data collection

A retrospective analysis of electronic patient charts was performed. The following data were collected: age, body mass index, preoperative prostate-specific antigen level, clinical stage (cT), biopsy Gleason score, preoperative physical state assessed by the American Society of Anesthesiologists physical status classification system (ASA), operation time, accomplishment of EPLND and nerve-sparing, pathologic Gleason score, tumor stage (pT), nodal and margin status, lymph node yield, weight of prostate specimen, presence of anastomotic leakage, day of catheter removal, duration of hospital stay, and postoperative complications. To assess bleeding, we recorded the estimated blood loss, the hemoglobin/thrombocyte levels before and after surgery, and the need for blood transfusions (red blood cells, fresh frozen plasma, or thrombocytes), with the number of administered units. Postoperative complications were graded according to the Clavien–Dindo classification.[13]

Blood count and pathological evaluation

Total blood count, including hemoglobin and thrombocytes, was routinely performed preoperatively and on the first day after surgery. For further analysis of the hemoglobin and thrombocyte course, the median drop was chosen as the cutoff value (2.9 g/dL and 54×10^3 platelets/μL). The pathological tumor stage, Gleason score, surgical margin, and lymph node status were retrieved from the pathology report of the Institute of Clinical Pathology of the University Hospital Zürich. Detailed comprehensive pathologic analysis was performed using standardized whole-mount sections. If tumor cells were detectable at the inked surface, the surgical margins were considered positive.[14]

Statistical analysis

PASW version 18.0 (SPSS Inc., Chicago, IL) was used for statistical analyses. The OAT group and the control group were compared using Fisher's exact test for categorical variables and the Mann–Whitney U test for continuous variables. All P values are two-sided and are considered significant for $P \leq .05$.

Results

Descriptive analysis

In total, 114 patients were included in this analysis. Thirty-eight patients received an RARP with continued OAT (100 mg of aspirin/day). All but 2 of the patients received aspirin for secondary prophylaxis after cardiac or cerebrovascular events. These 2 patients received aspirin for idiopathic

thrombocythemia or for primary prophylaxis. Matching of the two groups resulted in comparable preoperative baseline parameters except for different rates in ASA grading (Table 1): the percentage of patients classified as ASA III was significantly higher in the OAT group compared with the control group (15.8% versus 4.3%; $P = 0.001$).

Intraoperative parameters are presented in Table 2. EPLND was performed in 84.2% of cases, and nerve-sparing was performed in 42.1% of cases (matched variables). The mean operation time was comparable between the two groups (229 ± 55 minutes versus 253 ± 58 minutes, $P = .15$). RARP was completed in all OAT patients without conversion to open surgery. In 1 patient from the control group, the operation was converted to open prostatectomy because of extensive intra-abdominal adhesions after a previous abdominal surgery. No significant difference in the estimated intraoperative blood loss (271 ± 172 mL in the OAT group versus 345 ± 282 mL in the control group; $P = 0.21$), decrease of hemoglobin levels (-2.9 ± 1.4 g/dL versus -2.9 ± 1.1 g/dL; $P = 0.93$), or decrease of thrombocyte levels ($-47 \pm 90 \times 10^3/\mu$L versus $-55 \pm 30 \times 10^3/\mu$L; $P = .70$) could be observed.

The postoperative results are presented in Table 3. No significant differences were detectable between the two groups. Two patients in the OAT group, both taking aspirin because of coronary heart disease and coronary stenting, received blood transfusions postoperatively. One of these patients received 2 units of packed red blood cells on the first postoperative day; this patient had a hemoglobin level of 6.4 g/dL and was in a hemodynamically stable condition. Clinically, no source of bleeding could be detected, but because of a postoperative international normalized ratio (INR) of 2.0 (preoperatively 1.0), 1 unit of fresh frozen plasma and intravenous vitamin K were administered. A sufficient increase of the hemoglobin level was achieved (9.5 g/dL on the second postoperative day), and no further transfusion was necessary. The other of these 2 patients received 1 unit of packed red blood cells on the first postoperative day; this patient had a hemoglobin level of 8.0 g/dL (preoperatively 13.6 g/dL) and complained of dizziness. A second unit was administered on the second postoperative day because of a further decrease of the hemoglobin level to 7.5 g/dL. The dizziness improved quickly, and the hemoglobin level increased to 9.5 g/dL. Again, clinically, no source of bleeding could be detected. In the control group, no patient received

Table 1. Preoperative Data

	OAT group (n = *38*)	*Control* (n = *76*)	P
Age (years)	64.6 ± 5.7	63.6 (± 6.8)	.55
Body mass index (kg/m^2)	27.6 ± 4.1	26.4 ± 3.2	.21
Clinical stage			
pT1	26 (68.4%)	47 (61.8%)	.27
pT2	10 (26.3%)	28 (36.8%)	
pT3b	2 (5.3%)	1 (1.3%)	
Preoperative PSA (ng/mL)	7.0 ± 3.0	9.8 ± 8.0	.08
Gleason biopsy score			
5–6	8 (21.1%)	19 (25%)	.75
7	20 (52.6%)	42 (55.3%)	
8–10	10 (26.3%)	15 (19.7%)	
ASA physical status classification			
I	0 (0%)	18 (26.1%)	< .001[a]
II	32 (84.2%)	48 (69.6%)	
III	6 (15.8%)	3 (4.3%)	

Data are mean ± standard deviation values or number (%).
[a] P values ≤ .05 indicate a significant difference.
ASA, American Society of Anesthesiologists; OAT, oral antiplatelet therapy; PSA, prostate-specific antigen.

Table 2. Intraoperative Data

	OAT group (n = *38*)	*Control* (n = *76*)	P
Operation time (minutes)	229 ± 55	253 ± 58	.15
Estimated blood loss (mL)	271 ± 172	345 ± 282	.21
Lymph node dissection	32 (84.2%)	64 (84.2%)	1.00
Lymph node yield	19.4 ± 8.8	19.8 ± 9.1	.90
Positive nodal status	1 (3.1%)	7 (10.9%)	.26
Nerve-sparing			
None	22 (57.9%)	44 (57.9%)	1.00
One side	11 (28.9%)	22 (28.9%)	
Both sides	5 (13.2%)	10 (13.2%)	
Hemoglobin (g/dL)			
Preoperative	14.7 (0.9)	14.9 ± 0.9	.33
Postoperative	11.8 ± 1.4	12.0 ± 1.1	.63
Difference	− 2.9 ± 1.4	− 2.9 ± 1.1	.93
Hemoglobin difference			
< 2.9 g/dL	15 (39.5%)	40 (52.6%)	.23
≥ 2.9 g/dL	23 (60.5%)	36 (47.4%)	
Thrombocytes ($10^3/\mu$L)			
Preoperative	257.3 ± 89.5	251.7 ± 54.0	.53
Postoperative	213.74 ± 148.7	196.8 ± 44.6	.56
Difference	− 47.1 ± 90.4	− 55.8 ± 30.0	.70
Thrombocyte difference			
< 54 $10^3/\mu$L	17 (50%)	32 (43.2%)	.53
≥ 54 $10^3/\mu$L	17 (50%)	42 (56.8%)	

Data are mean ± standard deviation values or number (%).
OAT, oral antiplatelet therapy.

Table 3. Postoperative Data

	OAT group (n = *38*)	*Control* (n = *76*)	P
Transfusion rate			
Red blood cells	2 (5.3%)	0 (0%)	.11
Fresh frozen plasma	1 (2.6%)	0 (0%)	.33
Thrombocytes	0 (0%)	0 (0%)	
Gleason score			
5–6	4 (10.5%)	10 (13.2%)	.77
7	23 (60.5%)	49 (64.5%)	
8–10	11 (28.9%)	17 (22.4%)	
Pathologic stage			
pT2a-c	25 (65.8%)	50 (65.8%)	1.00
pT3ab	13 (34.2%)	26 (34.2%)	
Positive margin status			
pT2a-c	4 (16%)	7 (14%)	1.00
pT3ab	8 (61.5%)	12 (46.2%)	.50
Weight of prostate (g)	50.4 ± 19.4	51.5 ± 16.5	.54
Anastomotic leak	4 (10.5%)	8 (10.5%)	1.00
Catheter removal day (days)	6 ± 3	9 ± 10	.47
Hospital stay (days)	8 ± 3	9 ± 5	.19

Data are mean ± standard deviation values or number (%).
OAT, oral antiplatelet therapy.

Table 4. Complications According to the Clavien–Dindo Classification

Clavien	*OAT group* (n = *38*)	*Control* (n = *76*)	*Details*
Grade I	4 (10.5%)	14 (18.4%)	OAT group: 4 prolonged catheterizations (3 leakages, 1 urinary retention) Control group: 1 lymphocele, 1 reversible peripheral neurologic symptoms, 1 bedside wound opening, 11 prolonged catheterizations (7 leakages, 4 urinary retentions)
Grade II	4 (10.5%)	2 (2.6%)	OAT group: 1 paralytic ileus, 2 blood transfusions, 1 deep vein thrombosis Control group: 1 epididymitis, 1 SIRS with unknown focus
Grade III			
Grade IIIa	0	0	
Grade IIIb	0	1 (1.3%)	Control group: 1 urinoma requiring surgical intervention
Grade IV			
Grade IVa	0	0	
Grade IVb	0	0	
Grade V	0	0	
Total	8 (21.1 %)	17 (21.4%)	$P = 1.00$

OAT, oral antiplatelet therapy; SIRS, systemic inflammatory response syndrome.

blood transfusions. No further bleeding complications arose in the entire cohort. No patient developed adverse cardiovascular events intra- or postoperatively during hospitalization.

Only minor complications (Clavien–Dindo grade I–II) occurred in the OAT group (Table 4). Anastomotic leakage rates (10.5% versus 10.5%; $P = 1.00$) and total complication rates (21.1% versus 21.4%; $P = 1.00$) were equal with a mean hospitalization time of 8 days in both groups (8 ± 3 days and 8 ± 5 days; $P = .19$).

Pathologic evaluation

Evaluation of the collected specimens revealed that 65.8% of the patients had a pT2 tumor (matched variable; see Table 3). No significant difference in the distribution of the Gleason scores was observed ($P = .77$). The rate of positive surgical margins for localized tumors (pT2) was comparable in the two groups (16% versus 14%; $P = 1.0$). For pT3 tumors, the rate for positive surgical margins was 61.5% in the OAT group and 46.2% in the control group ($P = .50$).

Discussion

For a long time, it has been an accepted policy to stop antiplatelet treatment 7–10 days before surgery to avoid bleeding complications. Currently, it is known that this policy puts patients at an increased risk for thromboembolic events compared with patients with ongoing OAT during the operation.[5] The withdrawal of antiplatelet drugs generally results in a very high risk of major cerebro- and cardiovascular complications, such as myocardial infarction, stent thrombosis, and cerebral strokes, with a mortality rate of up to 45%.[4,15] The American Heart Association recommends dual antiplatelet therapy for the first 12 months following drug-eluting stent insertion.[6] Afterward, a lifelong continuation of low-dose aspirin for secondary prevention is recommended. In a meta-analysis performed by the Antithrombotic Trialists' Collaboration, secondary prevention with aspirin resulted in a 30% decrease of the myocardial re-infarction rate and a 25% decrease of the stroke rate.[16] OAT withdrawal not only results in the restoration of thrombocyte function, but also induces a rebound hypercoagulability with prothrombotic effects overcoming the physiological balance.[17,18] In a meta-analysis of 50,279 patients with OAT for the secondary prevention of coronary heart disease, the average delay between stopping aspirin and thrombotic events was 8.5 days.[19] This delay encompasses most of the time frame relevant to surgical procedures and thereby further increases the risk of intra- or perioperative cardiovascular events. Simultaneously, it is well known that surgical interventions promote thrombosis by increasing the synthesis of procoagulant clotting factors.[4] In a recently performed observational multicenter study with 1134 patients, the preoperative discontinuation of OAT for more than 5 days was an independent prognostic factor for major adverse cardiac and cerebrovascular events (odds ratio 2.11, 95% confidence interval 1.23–3.63; $P = .007$); however, continuation of OAT was not identified as a risk factor for major bleeding.[5]

Several investigations have reported an increased blood loss in noncardiac surgery of between 2.5% and 20% for patients who receive aspirin during the perioperative period.[4] It is notable that, except during intracranial surgery, no increase in surgical mortality and morbidity was observed. This is a key factor in weighing the consequences of aspirin continuation or withdrawal. Therefore, on the basis of the present evidence, although most trials regarding this issue have been observational and retrospective, perioperative continuation of aspirin has become increasingly supported in different medical fields.[4,20]

Previously, a retrospective analysis of patients undergoing open radical retropubic prostatectomy in 1990 detected a higher risk for bleeding in 52 aspirin-treated patients.[21] Because of ambiguous data about the safety of transurethral resection of the prostate (conventional electroresection), the recommendations for prostate surgery do not provide definite advice.[10,22,23] Considering the reports on blood loss in non-OAT patients, laparoscopic radical prostatectomy and RARP seemed to be promising techniques for the reduction of hemorrhagic complications. Although blood loss for radical retropubic prostatectomy ranged from 750 to 1284 mL, the

blood loss for laparoscopic radical prostatectomy was significantly reduced, ranging from 200 to 390 mL.[9] RARP again resulted in a slight but further decrease in blood loss, ranging from 50 mL to 273 mL.[9,24] Along with this development, significantly lower transfusion rates were reported.[9] Possible explanations for this reduction are the increased intra-abdominal pressure in minimally invasive approaches and, particularly in RARP, a combination of improved visualization and more intuitive handling of surgical instruments, leading to more precise preparation.

Recently, Nowfar et al.[25] presented the first study showing that RARP with aspirin therapy is feasible and not associated with an increased transfusion rate (0%). However, the OAT group in this study consisted of only 6 patients, limiting its statistical power and the conclusion. Subsequently, Parikh et al.[26] and Binhas et al.[27] presented their first data with larger cohorts regarding the implementation of laparoscopic radical prostatectomy/RARP under continuous OAT. They reported no significant differences in the transfusion rates and postoperative hemorrhagic complications. However, both studies reported significant differences in the preoperative parameters due to the lack of randomization or matching. Furthermore, no data on the oncological and early surgical outcome[26] or on the oncological outcome only[27] were presented.

To achieve comparable groups, we performed a matching of patients according to tumor stage, nerve-sparing, and lymphadenectomy. Each of these factors may have an independent influence on surgical margins or blood loss. Because of this matching, the preoperative parameters were equal or comparable.

In the present investigation, we have shown that RARP with low-dose aspirin therapy is feasible and safe. No major bleeding complications occurred intraoperatively, no procedures were converted to open surgery, and no patient in the OAT group required any type of postoperative invasive intervention (Clavien–Dindo classification grade III or higher). Two patients (5.3%) received blood transfusions, although both were hemodynamically stable. Furthermore, no limitations regarding tumor control (surgical margins, lymph node yield) or early surgical outcome (anastomotic leakage) were observed. Most important is that despite a high proportion of ASA III patients in the OAT group, no cardiovascular events occurred during the postoperative period.

The limitations of this analysis are its retrospective nature and, therefore, its lack of randomization. Without defined transfusion thresholds, a more liberal transfusion strategy in patients with preexisting cardiovascular disease cannot be ruled out. Additionally, because the surgeon was aware of the continued OAT, his decisions about the dissection and his estimation of the blood loss might have been influenced. However, we have nevertheless demonstrated a comparable outcome without a loss of clinical safety in RARP under continued OAT.

Conclusions

In general, the high risks and consequences of cardiovascular events after the withdrawal of antiplatelet drugs for secondary prevention outweigh the risk of intra- and postoperative bleeding due to continued antiplatelet treatment. Patients requiring antiplatelet therapy should therefore be evaluated individually and discussed with cardiologists and anesthesiologists before this vital prophylaxis is withdrawn prior to surgery.

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Disclosure Statement

No competing financial interests exist.

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